

K092161 FULL AUTOMATIC (NIBP) BLOOD PRESSURE MONITOR, MODEL HL868BFSep 30, 2009
76 days to decisionK092161 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k092161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 16, 2009
Decision date	Sep 30, 2009
Days to decision	76 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Health & Life Co., Ltd.
Location	Taipei Hsien, TW
Contact	SARAH SU
510(k) history	60 submissions · 60 cleared · 1999-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092161/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026